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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,624	08/05/2003	Marshall S. Kriesel	003 29	6579

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EXAMINER
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PRASAD, SONAL

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/634,624	<b>Applicant(s)</b> KRIESEL, MARSHALL S.	
	<b>Examiner</b> Sonal Prasad	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-5, 7-14, 22-21, 23, 24, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kriesel (US 5,743,879). Regarding claims **1 & 22**, Kriesel discloses a dispensing apparatus for dispensing fluids to a patient comprising: (a) an outer housing (detailed descrip 18, Fig. 15); (b) a first expandable housing disposed within said outer housing, said first expandable housing having a fluid reservoir provided with an inlet for permitting fluid flow into said fluid reservoir and an outlet for permitting fluid flow from said fluid reservoir (Fig. 15 & 24); (c) stored energy means disposed within said outer housing for exerting a force upon said first expandable housing to cause the fluid contained within said fluid reservoir to controllably flow through said outlet, said stored energy means comprising a compressively deformable, elastomeric member carried within said outer housing said, elastomeric member being expandable to cause fluid flow from said fluid reservoir (dd 6 & 7); (d) fill means carried by said outer housing for filling said reservoir with the fluid to be dispensed (dd 19); (e) modulating means carried by said outer housing for modulating the force exerted upon said first expandable housing by said stored energy means, said modulating means comprising a second expandable housing carried by said outer housing and operably associated with

said first expandable housing, and (dd 25) (f) dispensing means carried by said outer housing for dispensing fluid to the patient. (dd 19)

Regarding claim 2, Kriesel discloses the apparatus in which said elastomeric member comprises a yieldably deformable spring. (dd 25)

3. The apparatus as defined in claim 1 in which said first expandable housing comprises a bellows structure having an accordion-like side wall and, said bellows structure being movable from a substantially collapsed configuration to a substantially expanded configuration by fluid flowing into said fluid reservoir.

Regarding claim 4, Kriesel discloses the apparatus further including flow control means connected to said outer housing for controlling fluid flow between said reservoir and said dispensing means, said flow control means comprising a flow control member in fluid communication with said reservoir, said flow control member having a plurality of elongated flow control channels. (dd 29)

Regarding claim 5, Kriesel discloses the apparatus in which said fill means comprises a first fill vial receivable within said third portion of said outer housing. (dd 33)

Regarding claim 7, Kriesel discloses the apparatus in which said modulating means further includes impedance means disposed within said fluid outlet of said second expandable housing for controllably impeding the flow of the fluid contained within said fluid chamber outwardly thereof. (dd 33)

Regarding claim 8, Kriesel discloses the apparatus in which said impedance means comprises a porous frit. (dd 36)

Regarding claim **9**, Kriesel discloses the apparatus in which said fluid contained within said bellows structure comprises a gas. (dd 14)

Regarding claim **10**, Kriesel discloses a dispensing apparatus for dispensing fluids to a patient comprising: (a) an outer housing having first, second and third portions; (b) a first expandable housing disposed within said outer housing, said first expandable housing having a fluid reservoir provided with an inlet for permitting fluid flow into said fluid reservoir and an outlet for permitting fluid flow from said fluid reservoir, said first expandable housing comprising a bellows structure having an accordion-like side wall movable from a substantially collapsed configuration to a substantially expanded configuration by fluid flowing into said fluid reservoir; (c) stored energy means disposed within said second portion of said outer housing for exerting a force upon said inner expandable housing to cause the fluid contained within said fluid reservoir to controllably flow through said outlet, said stored energy means comprising a compressively deformable, spring member carried within said outer housing, said spring member being expandable to cause fluid flow from said fluid reservoir; (d) fill means carried by said outer housing for filling said reservoir with the fluid to be dispensed; (e) modulating means carried by said outer housing for modulating the force exerted upon said inner expandable housing by said stored energy means, said modulating means comprising a second expandable housing carried by said outer housing and operably associated with said first expandable housing, said second expandable housing comprising a bellows structure having an accordion-like side wall defining an air chamber for containing air, said second expandable housing having an outlet for

permitting the flow of air there through and being movable from a substantially expanded configuration to a substantially collapsed configuration by force exerted thereon by said spring member, (f) dispensing means carried by said outer housing for dispensing fluid to the patient; and (g) flow control means connected to said outer housing for controlling fluid flow between said reservoir and said dispensing means. (dd 36,38, & 44)

Regarding claim 11, Kriesel discloses the apparatus in which said fill means comprises a first inner vial receivable within said third portion of said outer housing and in which said third portion of said outer housing includes: (a) a fluid passageway; (b) a first chamber for telescopically receiving said first inner vial; and (c) an elongated support mounted within said first chamber, said elongated support having an elongated hollow needle, said hollow needle defining a flow passageway in communication with said fluid passageway. (dd 38 & 44)

Regarding claim 12, Kriesel discloses the apparatus in which said third portion of said outer housing includes a cavity in communication with said inlet of said fluid reservoir and in which said fill means comprises a pierceable septum disposed within said cavity. (Fig. 34)

Regarding claim 13, Kriesel discloses the apparatus in which said modulating means further includes impedance means disposed within said outlet of said second expandable housing for controllably impeding the flow of the air contained within said air chamber outwardly thereof. (Fig. 34)

Regarding claim **14**, Kriesel discloses the apparatus in which said flow control means comprises a flow control assembly including: (a) an inlet manifold having an inlet port in communication of with said outlet of said first expandable housing (dd 5); and (b) an outlet manifold connected to said inlet manifold, said outlet manifold having an elongated micro channel in communication with said inlet port of said inlet manifold and in communication with said dispensing means. (dd 5)

Regarding claim **23**, Kriesel discloses the apparatus in which said fill means comprises a first inner vial receivable within said third portion of said outer housing and in which said third portion of said outer housing includes: (a) a fluid passageway; (b) a first chamber for telescopically receiving said first fill vial; and an elongated support mounted within said first chamber, said elongated support having an elongated hollow needle, said hollow needle defining a flow passageway in communication with said fluid passageway. (dd 9)

Regarding claim **24**, Kriesel discloses the apparatus in which said outer housing includes a cavity in communication with said inlet of said fluid reservoir and in which said fill means comprises a pierceable septum disposed within said cavity. (dd 36)

Regarding claim **26**, Kriesel discloses the apparatus in which said flow control assembly further comprises: (a) an outer casing circumscribing said flow control member; and (b) distribution means formed in said flow control member for distributing fluid from said fluid reservoir to each of said plurality of elongated flow control channels. (dd 5 & 8)

Regarding claim **27**, Kriesel discloses the apparatus in which said flow control member is provided with an inlet passageway in communication with said fluid reservoir and in

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which said flow control assembly further includes filter means carried by said flow control member for filtering fluid flowing toward said distribution means. (dd 11)

Regarding claim 28, Kriesel discloses the apparatus in which said distribution means comprises a plurality of radially extending flow passageways formed in said flow control member. (dd 5 & 8)

Regarding claim 29, Kriesel discloses the apparatus in which said selector means comprises a selector knob connected to said flow control member, said selector knob having finger gripping means for imparting rotation to said selector knob to align said outlet of a selected one of said elongated flow control channels with said outlet of said fluid passageway in said second portion of said ullage defining member. ( dd 16 & 52)

Claims 15- 21, & 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kriesel (US 6,045,533). Kriesel discloses the apparatus in which said flow control means comprises a flow control assembly including: (i) an ullage-defining member having a first portion disposed within said first expandable housing and a second portion having a fluid passageway in communication with said outlet of said fluid reservoir (dd 14); (ii) a flow control member rotatably mounted within said first portion of said ullage defining member, said flow control member having a plurality of elongated flow control channels, each of said plurality of elongated flow control channels having an inlet and an outlet (dd12); and (iii) selector means rotatably connected to said second portion of said ullage defining member for rotating said flow control member to selectively align an



outlet of one of said elongated flow control channels with said fluid passageway in said second portion of said ullage defining member. (dd 19)

Regarding claim **16**, Kriesel discloses the apparatus in which said flow control assembly further comprises: (a) an outer casing circumscribing said flow control member (Fig 7); and (b) distribution means formed in said flow control member for distributing fluid from said fluid reservoir to each of said plurality of elongated flow control channels. (dd 20)

Regarding claim **17**, Kriesel discloses the apparatus in which said flow control member is provided with an inlet passageway in communication with said fluid reservoir and in which said flow control assembly further includes filter means carried by said flow control member for filtering fluid flowing toward said distribution means. (dd 20 & 26)

Regarding claim **18**, Kriesel discloses the apparatus in which said distribution means comprises a plurality of radially extending flow passageways formed in said flow control member. (dd 32)

Regarding claim **19**, Kriesel discloses the apparatus in which said selector means comprises a selector knob connected to said flow control member, said selector knob having finger gripping means for imparting rotation to said selector knob to align said outlet of a selected one of said elongated flow control channels with said outlet of said fluid passageway in said second portion of said ullage defining member. (dd 39)

Regarding claim **20**, Kriesel discloses the apparatus further including volume indicator means for indicating the volume of fluid remaining in said fluid reservoir. (dd 113)

Regarding claim **21**, Kriesel discloses the apparatus further including disabling means for preventing fluid flow toward said dispensing means. (claim 13)

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Regarding claim 25, Kriesel discloses the apparatus in which said flow control means comprising a flow control assembly including (i) an ullage-defining member having a first portion disposed within said first expandable housing and a second portion having a fluid passageway in communication with said outlet of said fluid reservoir; (ii) a flow control member rotatably mounted within said first portion of said ullage defining member, said flow control member having a plurality of elongated flow control channels, each of said plurality of elongated flow control channels having an inlet and an outlet, and (iii) selector means rotatably connected to said second portion of said ullage defining member for rotating said flow control member to selectively align an outlet of one of said elongated flow control channels with said fluid passageway in said second portion of said ullage defining member. (dd 20,26, &32)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kriesel (US 5,743,879). Making the structure an of the side wall an accordion shape would have been obvious to one of ordinary skill in the art as claimed is a mere design choice lacking any criticality of shape as being merely preferable aesthetics where the only difference between the prior art and the claims was a recitation of relative shape of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad  
Examiner  
Art Unit 3767

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A handwritten signature in black ink, appearing to read "M. J. Hayes", written in a cursive style.

MICHAEL J. HAYES  
PRIMARY EXAMINER